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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/539,842	
	Filing Date	June 20, 2005	
	First Named Inventor	MUNTAU-HEGER	
	Art Unit	1614	
	Examiner Name	VAKILI, Zohreh	
Total Number of Pages in This Submission	10	Attorney Docket Number	3535.020

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Akerman Senterfitt		
Signature	<i>Nicholas J. Landau</i>		
Printed name	Nicholas J. Landau, Ph.D.		
Date	11/02/2006	Reg. No.	57,120

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of MUNTAU-HEGER, *et al.*

Confirmation No. 5018

Application No. 10/539,842

Examiner: VAKILI, Zohreh

Filed: June 20, 2005

Group Art Unit: 1614

Attorney Docket No. 3535.020

For: USE OF TETRAHYDROBIOPTERINE DERIVATIVES IN THE TREATMENT  
AND NUTRITION OF PATIENTS WITH AMINO ACID METABOLIC DISORDERS

**INFORMATION DISCLOSURE STATEMENT**

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Nicholas J. Landau, Ph.D.

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P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, Applicants hereby notify the U.S. Patent Office of the documents which are listed on the attached Forms PTO/SB/08A and PTO/SB/08B.

Applicants submit that the present invention is patentable over the cited references and submission of the listed documents is not intended as an admission that such documents constitute prior art against the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove the listed documents as competent references against the present application.

The below references 2, 3, 9, 12, 13, 19, 22, 28, 31, and 33 were cited in the European Search Report issued in corresponding European application as "Category X," or of particular relevance. The references 2, 3, 6, 13, 19, 21, and 30 were cited in a European Office Action for the corresponding International Application. References 1 – 5, 7, 8, 10, 11, 13 – 15, 17, 18, 20, 23 – 17, 29, and 31 – 33 were cited in a Protest of the U.S. National Phase of International Application no. PCF/EP2003/014262 pursuant to 37 C.F.R. §1.291. Copies of U.S. references are not enclosed. A copy of each foreign language reference is enclosed, along with a English translation of the abstract, where available. A copy of the international search report and European Office Action (in German, as no English translation is available) are also enclosed.

Applicants respectfully request that the listed documents be considered by the Examiner and made of record in the present application and that an initialed copy of forms PTO/SB/08A and PTO/SB/08B be returned in accordance with MPEP §609.

1. U.S. Patent No. 4,774,244
2. U.S. Patent No. 4,778,794
3. U.S. Publication No. 2002/0052374 A1
4. U.S. Patent No. 5,763,392
5. U.S. Patent No. 6,428,990 B1
6. WO 1995/13803
7. BATES, et al., "Children's Medications: A Parent's Guide", page 6, Harvery Whitney Books, Cincinnati, Ohio, (1996).
8. BLAU, et al., "34th EMG Meeting, Zurich CH, held May 31-June 2, 2003", proceedings published October 2002.
9. BERNEGGER, et al., "High frequency of tetrahydrobiopterin-responsiveness among hyperphenylalaninemias...", Molecular Genetics and Metabolism, 77:304-313 (2002).

10. CURTIUS, et al., *The Lancet*, 1:657-658 (March 19,1983).
11. CURTIUS, et al., "Therapeutic Efficacy of Tetrahydrobiopterin in Parkinson's Disease", *Advances in Neurology*, 40:463-466 (1984).
12. CURTIUS, et al., "Atypical Phenylketonuria due to Tetrahydrobiopterin...", Elsevier/North-Holland Biomedical Press, 93:251-252 (1979).
13. DISSING, et al., "Tetrahydrobiopterin and Parkinson's Disease", *Acta Neurol. Scand.*, 79:493-499 (1989).
14. ELLIS, JOHN R., "The general concept of molecular chaperones", *Phil. Trans. R. Soc. Lond. B*, 339:257-261 (1993).
15. ERLANDSEN, et al., "A structural hypothesis for BH4 responsiveness in patients...", *J. Inherit. Metab. Dis.* 24:213-230 (2001).
16. FURUKAWA, et al., "Striatal biopterin and tyrosine hydroxylase protein reduction dopa-responsive dystonia", *Neurology*, 53:1032-1041 (1999).
17. HENNERMANN, et al., "Partial and Total Tetrahydrobiopterin-responsiveness in classical and mild phenylketonuria (PKU)", *J. Inherit. Metab. Dis.*, Suppl. 1:1-184 (2002).
18. ISAACS, JOHN, "Helping the Medicine Go Down", *American Druggist*, 37-41 (1999).
19. KITAGAWA, et al., "A Nation-wide Study of Tetrahydrobiopterin- responsive Phenylalanine...", *J. Inherit. Metab. Dis.* Suppl. 1: 24 (2001).
20. KURE, et al., "Tetrahydrobiopterin-responsive phenylalanine hydroxylase deficiency", *The Journal of Pediatrics*, 135:375-8 (1999).
21. MILLER, et al., "Role of Hydroxylase Cofactor in Regulating Dopamine Synthesis: Relevance to Neurological Disorders", 471-474 (1986).
22. MUNTAU, et al., "Tetrahydrobiopterin as an Alternative Treatment for Mild Phenylketonuria", *N Engl J Med*, 347-26:2122-32 (2002).

23. NAGATSU, TOSHIHARU, "Tyrosine hydroxylase: human isoforms, structure and regulation in physiology and pathology", *Essays in Biochemistry*, 30:15-35 (1995).
24. "PhenylAde", Product Guide, Applided Nutrition Corp., (November 2002).
25. "PhenylAde", Product Guide, Applided Nutrition Corp., (May 2002).
26. SCHAUB, et al., "Tetrahydrobiopterin therapy of atypical phenylketonuria due to defective dihydrobiopterin biosynthesis", *Archives of Disease in Childhood*, 53:674-683 (1978).
27. SHINOZAKI, et al., "Oral Administration of Tetrahydrobiopterin Prevents Endothelial Dysfunction..." *Circulation Research*, 87:655-73 (2000).
28. STEINFELD, et al., "A hypothesis on the biochemical mechanism of BH4-responsiveness in phenylalanine hydroxylase deficiency", *Amino Acids*, 25:63-68 (2003).
29. STEINFELD, et al., "Tetrahydrobiopterin monotherapy for phenylketonuria patients with common mild mutations", *Eur J Pediatr*, 161:403-5 (2002).
30. TANAKA, et al., "On-off phenomenon in a child with Tetrahydrobiopterin deficiency due to 6-pyruvoyl tetrahydropterin synthase...", *Eur J Pediatr*, 148:450-52 (1989).
31. TREFZ, et al., "Successful treatment of phenylketonuria with tetrahydrobiopterin", *Eur J. Pediatr*, 160:315 (2001).
32. WALTER, et al., "Inhalation of the Nitric Oxide Synthase Cofactor Tetrahydrobiopterin in Health Volunteers", *Am J Respir Crit Care Med*, 156: 2008-10 (1997).
33. WEGLAGE, et al., "Tetrahydrobiopterin responsiveness in a large series of phenylketonuria patients", *J. Inherit. Metab. Dis.* 25:321-322 (2002).

Certification

This Statement is being filed prior to the issuance of the first Office Action for the present application, and this paper is thus submitted in accordance with 37 C.F.R. 1.97(b).

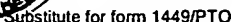
In view of the above certification, a fee is not required for consideration of this document. Nevertheless, should a fee be deemed to be due by the Commissioner, such fee should be charged to Deposit Account No. 50-0951.

Respectfully submitted,

Dated: 11/02/2006

Nicholas J. Landau  
Nicholas J. Landau, Ph.D.  
Reg. No. 57,120  
**AKERMAN SENTERFITT**  
Post Office Box 3188  
West Palm Beach, FL 33402-3188  
Tel: 561-653-5000

Docket No. 3535.020



*(Use as many sheets as necessary)*

Sheet	1	of	4
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**Complete if Known**

Application Number	10/539,842
Filing Date	June 20, 2005
First Named Inventor	MUNTAU-HEGER
Art Unit	1614
Examiner Name	VAKILI, Zohreh
Attorney Docket Number	3535.020

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> *Number <sup>4</sup> *Kind Code <sup>5</sup> (if known)				
		WO 1995/13803	05-26-1995	CORNELL RESEARCH		

Date Considered

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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### Complete if Known

Application Number	10/539,842
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First Named Inventor	MUNTAU-HEGER
Art Unit	1614
Examiner Name	VAKILI, Zohreh
Attorney Docket Number	3535.020

Sheet 2 of 4

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BATES, et al., "Children's Medications: A Parent's Guide", page 6, Harvery Whitney Books, Cincinnati, Ohio, (1996).	
		BLAU, et al., "34th EMG Meeting, Zurich CH, held May 31-June 2, 2003", proceedings published October 2002.	
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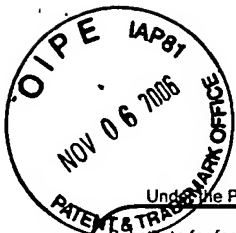
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Sheet	3	of	4

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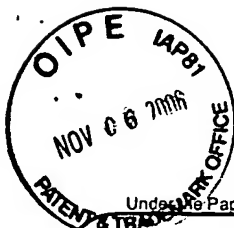
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Sheet 4 of 4

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